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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,773	01/26/2004	Hrair Kirakossian	138.00US	2462
70464	7590	10/04/2007		
MONOGRAM/FENWICK SILICON VALLEY CENTER 801 CALIFORNIA STREET MOUNTAIN VIEW, CA 94041			EXAMINER DO, PENSEE T	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 10/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/765,773

Applicant(s)

KIRAKOSSIAN ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8, 11, 12 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8, 11, 12, 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 20, 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-8, 11, 12, 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is unclear if the cell surface antigen is one of the proteins in the protein-protein complex.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-8, 11, 12, 17-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 19, 25, 28-30 of U.S. Patent No. 7,105,308 in view of Terstappen et al. (US 6,365,362).

Patent '308 teaches a method of detecting a dimer in a sample comprising mixing the sample containing the dimer, a cleaving probe comprising a first binding compound which has a cleavage-inducing moiety, and is specific to the first component of the dimer, and a second binding compound attached with molecular tags via a cleavable linkage within an effective proximity of the cleaving inducing moiety of the cleaving probe and is specific for the second component of the dimer; separating and detecting the released tags thus detecting the dimer. Separation of the released tags is by electrophoretic mobility. The receptor dimer is one or more ErbB receptors such as Her1, Her 2, Her 3 and Her 4.

However, Patent '308 differs from the present invention in failing to teach a magnetic separation step for the sample preparation before carrying out the assay to isolate rare cell types such as cancer cells, fetal cells from patient biological sample such as culture, blood, saliva, etc. as recited in claims 19-20.

Terstappen teaches a method for screening rare cells such as fetal or cancer cells in a biological sample (see col 6, lines 6-7) by contacting a biological sample containing a mixed cell population suspected of containing the rare cell of interest with magnetic particles coupled to a biospecific ligand (antibody) reactive with a rare cell determinant (capture antigen) or a class of determinants different than those found on blood cells; subjecting the resulted immunomagnetic sample to a magnetic field which is effective to separate the sample into an unlabeled fraction and a labeled, magnetic fraction including rare cell determinant. A second set of monoclonal antibodies, labeled with reporter molecules, are added to the sample and the cells are again magnetically separated in order to remove unbound reagent. Identifying the reporter. (see col. 7, line 45-col. 8, line 53).

It would have been obvious to one of ordinary skills in the art to isolate the mixed population of cells as taught by Terstappen before detecting biomarkers of rare cell type using the method of patent '308 since biomarkers or determinants on cell surface is considered cell surface protein and such isolation of subpopulation of cells would reduce non-specific binding and increase sensitivity in the detection of rare cell type.

Claims 4-6, 11, 12 and 17-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 8, 20, 21 of U.S. Patent No. 7,135,300 in view of Terstappen et al. (US 6,365,362).

Patent '300 teaches a method of detecting a dimerization profile among a plurality of receptor types comprising mixing the sample containing the dimer, a cleaving probe comprising a first binding compound which has a cleavage-inducing moiety, and

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is specific to the first component of the dimer, and a second binding compound attached with molecular tags via a cleavable linkage within an effective proximity of the cleaving inducing moiety of the cleaving probe and is specific for the second component of the dimer; separating and detecting the released tags thus detecting the dimer. Separation of the released tags is by electrophoretic mobility. The receptor dimer is one or more receptors such as Her1, Her 2, Her 3 and Her 4.

Patent 300 differs from the present invention in failing to teach a magnetic separation step for the sample preparation before carrying out the assay to isolate rare cell types such as cancer cells, fetal cells from patient biological sample such as culture, blood, saliva, etc. as recited in claims 19-20.

Terstappen teaches a method for screening rare cells such as fetal or cancer cells in a biological sample (see col 6, lines 6-7) by contacting a biological sample containing a mixed cell population suspected of containing the rare cell of interest with magnetic particles coupled to a biospecific ligand (antibody) reactive with a rare cell determinant (capture antigen) or a class of determinants different than those found on blood cells; subjecting the resulted immunomagnetic sample to a magnetic field which is effective to separate the sample into an unlabeled fraction and a labeled, magnetic fraction including rare cell determinant. A second set of monoclonal antibodies, labeled with reporter molecules, are added to the sample and the cells are again magnetically separated in order to remove unbound reagent. Identifying the reporter. (see col. 7, line 45-col. 8, line 53).

It would have been obvious to one of ordinary skills in the art to isolate the mixed population of cells as taught by Terstappen before detecting biomarkers of rare cell type using the method of patent '300 since biomarkers or determinants on cell surface is considered cell surface protein and such isolation of subpopulation of cells would reduce non-specific binding and increase sensitivity in the detection of rare cell type.

Remarks

Claims 4-8, 11, 12, 17-20 are free of prior arts.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pensee T. Do
Patent Examiner
September 27, 2007


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